

Patient Leaflet According to the Pharmacists' Regulations (Preparations) – 1986

This medicine is sold with a doctor's prescription only.

Betistine 16 mg

Tablets

Active ingredient:

Each tablet contains: 16 mg of betahistine hydrochloride.

For the list of the additional ingredients, see section 6. See also 'Important information about some of the medicine's ingredients' in section 2.

Read this entire leaflet carefully before using the medicine. This leaflet contains concise information about the medicine. If you have any further questions, please refer to your doctor or pharmacist.

This medicine has been prescribed for your treatment. Do not pass it on to others. It may harm them, even if it seems to you that their medical condition is similar to yours.

1. What is the medicine intended for?

For treatment of Ménière's syndrome.

For treatment of peripheral vertigo.

Therapeutic group: anti-vertigo medicines.

The medicine contains betahistine which is a histamine analog used for treatment of Ménière's syndrome symptoms, which include: dizziness (vertigo), ringing in the ears (tinnitus), hearing loss, hearing difficulties.

The medicine acts by improving the blood flow in the inner ear, thereby reducing pressure buildup.

2. Before using the medicine

Do not use the medicine if:

- You are sensitive (allergic) to the active ingredient (betahistine) or to any of the other ingredients the medicine contains (for the list of the additional ingredients, see section 6).
- You suffer from a tumor in the adrenal gland (pheochromocytoma).

Special warnings regarding the use of this medicine:

Before (and during) treatment with Betistine, inform your doctor if:

- You suffer from asthma (your doctor may wish to monitor your asthma condition during the treatment).
- You suffer or have suffered in the past from a stomach ulcer.
- You are pregnant, think you are pregnant or planning a pregnancy.
- You are breastfeeding.

If one of the conditions described above is relevant to you, your doctor will advise you whether you can use the medicine.

Children and adolescents

Betistine is not recommended for use in children and adolescents under 18 years of age since there is insufficient data on the safety and efficacy of the medicine in this age group.

Drug interactions

If you are taking, or have recently taken any other medicines, including non-prescription medicines and nutritional supplements, please tell your doctor or pharmacist. Especially inform your doctor or pharmacist before and during treatment with Betistine if you are taking:

- Medicines from the monoamino-oxidase inhibitor group (MAOIs) for treatment of depression or Parkinson's disease. These medicines may increase the effect of Betistine.
- Antihistamines: These medicines may reduce the effect of Betistine. Betistine may also reduce the effect of antihistamines.

Use of this medicine and food

It is recommended to take Betistine with food or after eating.

Pregnancy and Breastfeeding

- Do not take Betistine during pregnancy unless your doctor decided that this is essential.
- It is not known whether the medicine passes in breastmilk. Do not breastfeed during treatment with Betistine, unless your doctor instructed you to do so.

Driving and use of machinery

The medicine should not affect your ability to drive or to use tools or machinery.

However, the symptoms of the diseases for which the medicine is intended (vertigo, tinnitus, hearing loss, dizziness, nausea) may negatively affect your ability to drive and operate machinery.

Important information about some of the ingredients of the medicine

Each tablet contains approximately 140 mg lactose. If you have intolerance to certain sugars, consult your doctor before taking this medicine.

3. How to use this medicine?

Always use the medicine according to the doctor's instructions. Check with the doctor or pharmacist if you are not sure regarding the dosage and manner of treatment with the medicine. The dosage and manner of treatment will be determined by the doctor only.

The doctor will adjust your dosage according to your medical condition. The medicine may not have an immediate effect.

The standard dosage for adults is usually: 16 mg three times daily.

If necessary, it is possible to start with a dosage of 8 mg three times daily. If an 8 mg dosage is required, the tablet may be halved according to the scored line imprinted on the tablet.

The daily dose varies between 24 to 48 mg; it is recommended to divide it equally into three doses over the day in order to ensure that the level of medicine in your body is fixed.

Try to take the tablets at set times every day.

Do not exceed the recommended dose.

Swallow the medicine with water. It is recommended to take the medicine with food.

There is no information on crushing or chewing the tablets. The tablets may be halved according to the scored line imprinted on the tablet.

If you accidentally took a higher dosage:

If you have taken an overdose or if a child has accidentally swallowed the medicine, refer immediately to a doctor or a hospital emergency room and bring the medicine package with you.

If you forgot to take the medicine

If you forgot to take this medicine at the designated time, do not take a double dose to compensate for the forgotten dose. Take the next dose at the usual time and consult your doctor.

Adhere to the treatment as recommended by your doctor. Even if there is an improvement in your health condition, do not stop the treatment with the medicine without consulting the doctor.

Do not take medicines in the dark! Check the label and the dose each time you take a medicine. Wear glasses if you need them.

If you have further questions concerning the use of the medicine, consult the doctor or pharmacist.

4. Side effects

As with any medicine, the use of Betistine may cause side effects in some users. Do not be alarmed when reading the list of side effects. You may not suffer from any of them.

Stop treatment and refer to your doctor immediately if the following side effects appear:

Allergic reactions such as:

- Red skin rash, skin inflammation and irritation.
- Swelling of the face, lips, tongue or throat. These side effects may cause breathing difficulties.

Common side effects (appear in 1-10 users out of 100):

Nausea, digestion difficulties, headaches.

Additional side effects:

Irritation, rash, hives (allergic reactions of skin blood vessels).

Mild digestive system disorders such as vomiting, abdominal pains and abdominal bloating.

Taking the medicine with food will help reduce these effects.

If a side effect appears, if one of the side effects worsens, or you suffer from a side effect not mentioned in the leaflet, consult with your doctor.

Side effects may be reported to the Ministry of Health by clicking on the link "Report on side effects following medicinal treatment" on the homepage of the Ministry of Health website (www.health.gov.il) which leads to the online form for reporting side effects, or by entering the link:

<https://sideeffects.health.gov.il/>

5. How to store the medicine?

- Avoid poisoning! This medicine, and any other medicine, must be stored in a closed place out of the reach and sight of children and/or infants, to avoid poisoning. Do not induce vomiting unless explicitly instructed to do so by the doctor.
- Do not use the medicine after the expiry date (exp. date) that appears on the package. The expiry date refers to the last day of that month.
- Storage conditions: store in the original package below 25°C.

6. Additional information

In addition to the active ingredient, the medicine also contains:

Lactose monohydrate, microcrystalline cellulose, crospovidone, stearic acid, colloidal silicon dioxide, povidone k90.

What does the medicine look like and what does the package contain?

Round white tablets. On one side a scored line is imprinted and on the other side 'B16' is imprinted. The tablets are packaged in blister packs, 30 tablets per box.

Registration holder: Rafa Laboratories Ltd., P.O. Box 405, Jerusalem 9100301

Medicine registration number in the National Medicines Registry of the Ministry of Health:
1207630126

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